

Statement by the American Medical Women's Association

Thank you for the opportunity for the American Medical Women's Association (AMWA) to submit written comments regarding the interest of the Food and Drug Administration (FDA) in the approval of over-the-counter drug products. AMWA is a national organization of 10,000 women physicians and medical students dedicated to promoting women's health and to the advancement of women physicians. We feel that the issue of over-the-counter drug product availability and its regulation are critical components to women's health. I am grateful to be able to submit written comments on behalf of AMWA on this issue.

The issue

AMWA is in favor of the concept of over-the-counter drug product use for asymptomatic as well as symptomatic conditions when the drugs are shown to be safe and effective in unmonitored situations. We recognize that many of the risk factors and conditions that occur in women, especially those outside of reproductive health, are often under-recognized and undertreated by members of the medical profession. We also recognize the conditions in reproductive health where timely medical care is not always immediately available. We realize that, for too many women, health care coverage provides reimbursement only for illnesses and not for routine examinations, potential health concerns or health screening to identify and monitor their risk factors. Numerous studies have been published and countless articles have been written detailing the disparities in risk factor evaluation and treatment that occur in women, even for potentially serious risk factors or life-changing medical problems. Since efforts that increase the availability of options for treatment of these risk factors and conditions are crucial to improving women's health, we feel that FDA approved over-the-counter drug product availability, including for the treatment of asymptomatic conditions, will give women the options they need for improving their health and health care.

Safety standards

Any medication being considered for transfer to over-the-counter use should be shown to have safety in use with very low incidence of side effects or organ complications comparable or nearly comparable to placebo in patients with the clinical conditions for which it is prescribed. Because over-the-counter medications may be self-prescribed and self-monitored, package and labeling instructions should include detailed descriptions of the less common and of the more serious potential side effects along with information on when to seek medical attention should these side effects occur. We feel that the issues of safety and efficacy that should be addressed when reviewing all over-the-counter drug product use should adhere to similar standards regardless of the conditions the drug product is to be used for, whether symptomatic or asymptomatic, acute or chronic.

Monitoring of efficacy

When over-the-counter drug products are used, patients are not necessarily seeking frequent medical evaluation or professional follow-up of their conditions. The efficacy of

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over-the-counter drug product use may not always be apparent to patients, especially drug products used for conditions without active and current symptoms that respond acutely to the use of the over-the-counter drug products.

We recognize that patients may more easily self-monitor efficacy of drug use for symptomatic conditions when the drug use is for active and current symptoms, as their use can be clearly followed by a change or resolution of symptoms with efficacious use, providing the patient helpful feedback. It is important to recognize that patients self-medicate for many symptomatic conditions but do not always experience active and current symptoms that cause them to change their drug product use. Therefore, the ability to easily self-monitor efficacy based on symptoms does not necessarily exist, even for drug products used for symptomatic conditions. This is an important point to acknowledge when the issue of over-the-counter drug product use is compared for symptomatic versus asymptomatic conditions.

In the settings of asymptomatic conditions and symptomatic conditions where the drug product use is not for active and current symptoms, no obvious symptoms exist by which the patients can monitor their need for use. In these situations, the easy feedback that patients depend upon for acute symptoms is not accessible. This does not mean that asymptomatic conditions should not be treated with over-the-counter medication. It is with the treatment of conditions when they are asymptomatic that the medical profession is able to exert the greatest benefit to the largest number of people by preventing or forestalling the development of symptomatic conditions.

Regardless of their reason for use, patients need clear information on the package or labeling as to how they can obtain monitoring of the efficacy of the drug product in use. Included in this information should be a description of which evaluations or tests are appropriate to discuss with their health care provider at the time of a medical visit in order to evaluate efficacy.

Examples

In non-reproductive women's health, our awareness is rapidly increasing about the benefits of over-the-counter drug product use for many asymptomatic conditions and symptomatic conditions where the drug product use is not for active and current symptoms. We currently recommend many non-prescription treatments for such conditions. We recommend over-the-counter drug product or non-prescription treatments using drugs or supplements to prevent or treat asymptomatic conditions including calcium and Vitamin D supplementation for osteoporosis prevention and treatment, folic acid supplementation for the prevention of birth defects and reduction of heart disease risk and certain margarine products to reduce cholesterol elevations associated with increased heart disease risk. We also recommend over-the-counter drug product use to prevent or treat symptomatic conditions, whether or not the patient is experiencing active and current symptoms where the drug product use may be adjusted based upon current symptoms. Notable examples include the recommendation to use low dose aspirin both for the prevention of recurrent strokes

and for the prevention of recurrent myocardial infarction and cardiac death. In each of these situations, efficacy cannot be self-monitored.

In reproductive women's health, we have already seen the benefit of over-the-counter drug product use for both asymptomatic conditions and symptomatic conditions with and without acute symptoms to preserve reproductive options and health. We recommend over-the-counter drug product use including anti-fungal medications for vaginal yeast infections and vaginal products for contraception.

Barriers

In non-reproductive women's health, many of these asymptomatic conditions are of particular interest as they are often under-appreciated or undertreated by health care providers. The ability for women to reduce their risk for the development of symptomatic conditions with or without active and current symptoms with the use of over-the-counter drug products enables women to use their interest in self-help therapies and their awareness of their personal risk factors to improve their health risks. Women need options. Over-the-counter drug products for non-reproductive health provide women options for self-care and the opportunity to look after their personal health.

In reproductive women's health, the greatest barrier women face is the unwillingness of some health care providers, both non-gynecological and some gynecological, to offer treatment for commonly occurring conditions, especially on a timely basis. This can lead to the loss of options for women, especially in the control of their reproductive future. Women need options. Over-the-counter drug products for reproductive health provide women options for self-care and the opportunity to look after their personal reproductive health.

We must acknowledge that every patient does not have the opportunity to fully discuss all of her perceived risk factors and all of her fears with her health care professional on a regular basis. Very often health care interactions are limited to acute visits for acute medical conditions. This may be due in part to the failure of most insurance plans to cover the costs of well visits and general health counseling or the refusal of health plans to cover a wide variety of risk factor screening. This also may be due in part to a lack of recognition by health care professionals of an individual's risk or their willingness to be evaluated for or treated for risk factors for asymptomatic conditions. This may also be due, in part, to unwillingness on the part of certain health care professionals to make treatment available to their women patients because of their own biases or misinformation. This may also be due to the unwillingness of many women to acknowledge their health risks to a health care provider or to take the time out of their busy schedules for medical evaluations that are not focused upon acute problems.

Conclusion

Because of AMWA's interest in improving women's health and our belief that certain prescription medications may be safely and efficaciously used in the over-the-counter setting by individuals with an awareness to discern personal risk factors for

asymptomatic as well as symptomatic conditions with or without acute and current symptoms, the American Medical Women's Association endorses the concept of the use of over-the-counter medications and urges the FDA to proceed with the appropriate evaluations of those prescription medications, including those for asymptomatic conditions, that may be safely and efficaciously used in the over-the-counter setting.

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